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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,950	03/19/2004	Christine Konradi	04843/120003	8080

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EXAMINER	
SALMON, KATHERINE D	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,950	KONRADI ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups I-XII are subject to further restriction, see Section 21.

I. Claims 1-2, drawn to a microarray comprising at least two nuclear encoded mitochondrial energy metabolism **nucleic acid** molecules, classified in class 435, subclass 287.2.

II. Claim 3, drawn to a microarray comprising at least two nuclear encoded mitochondrial energy metabolism **polypeptides**, classified in class 435, subclass 287.2.

III. Claims 4-5 and 8-9, 10, 12, 13 drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a nuclear encoded mitochondrial energy metabolism **nucleic acid** molecule, classified in class 435, subclass 6.

IV. Claims 6-7 and 8-9, 11, 12, 14 drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a nuclear encoded mitochondrial energy metabolism **polypeptide**, classified in class 435, subclass 7.1.

V. Claims 15, 16, drawn to a microarray comprising at least two **nucleic acid** molecules which encode a proteasomal polypeptide, classified in class 435, subclass 287.2.

VI. Claim 17, drawn to a microarray comprising at least two proteasomal **polypeptides**, classified in class 435, subclass 287.2.

VII. Claims 18, 19, 22, 23, 25, drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a **nucleic acid** that encodes a proteasomal polypeptide in class 435, subclass 6.

VIII. Claims 20, 21, 22, 24, 26 drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a proteasomal **polypeptide** in class 435, subclass 7.1.

IX. Claims 27, drawn to a microarray comprising at least two **nucleic acid** molecules listed in Table 4, or fragments thereof, bound to a solid support in class 435, subclass 287.2.

X. Claims 28, drawn to a microarray comprising at least two **polypeptides** listed in Table 4, or fragments thereof, bound to a support in class 435, subclass 287.2.

XI. Claims 29, 30, 33, 34, 36, 37 drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a **nucleic acid** listed in Table 4 in class 435, subclass 6.

XII. Claims 31, 32, 33, 35, 38 drawn to a method of diagnosing, monitoring, identifying, or ameliorating comprising determining the level of expression of a **polypeptide** encoded by a nucleic acid listed in Table 4 in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I, II, III, and IV) and (V, VI, VII, and VIII) and (IX, X, XI, and XII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Inventions (I, II, III, and IV) are drawn to products and methods of nuclear encoded mitochondrial energy metabolism polypeptides or nucleic acids. Inventions (V, VI, VII, and VIII) are drawn to products and methods using fragments of nucleic acids or polypeptides of proteasomal molecules. Inventions (IX, X, XI, and XII) are drawn to products and methods of fragments of nucleic acids or polypeptides of genes from Table 4. There is no indication in the claims that Inventions (I, II, III, and IV) and (V, VI, VII, and VIII) and (IX, X, XI, and XII) are used together and therefore there is no relationship between the inventions. For example there is no indication in the claims that the nucleic acid array containing fragments of nuclear encoded mitochondrial energy metabolism molecules is used in the method of Invention VII drawn to a method of determining the level of expression of a nucleic acid that encodes a proteasomal polypeptide.

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case Invention I is drawn to an array of nucleic acids of mitochondrial energy metabolism nucleic acid molecule and Invention II is drawn to a polypeptide array of mitochondrial energy metabolism. The inventions share a common step in which both the nucleic acids and polypeptides are bound to an array, however, the inventions are distinct because they are drawn to patentably distinct products, which have different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phospodiester bonds and assumes the form of a double helix. The polypeptides of Group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The reagents, reaction conditions, and reaction parameters for nucleic acid arrays and polypeptide arrays are different from each other. The search for each of the groups presents a serious search burden, as the searches for each are not coextensive in scope. Art describing polynucleotides would not necessarily describe polynucleotides of the same fragments, and vice versa.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of nuclear encoded mitochondrial energy metabolism molecules could be used in the method of determining the level of expression or can be used in a haplotyping method. The search for each invention presents a serous burden, as the searches for each are

not coextensive in scope. Art relating to the methods of determining the level of expression would not necessarily provide descriptive information on the nucleic acid array itself, and vice versa.

5. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid microarray and a method of measuring expression levels of a polypeptide microarray. There is no indication in the claims that the product of Invention I is used in the method of Invention IV and therefore there is no relationship between the two inventions.

6. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a polypeptide microarray and a method of measuring expression levels of a nucleic acid microarray. There is no indication in the claims that the product of Invention II is used in the method of Invention III and therefore there is no relationship between the two inventions.

7. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of nuclear encoded mitochondrial energy metabolism molecules could be used in the method of determining the level of expression or can be used in an antibody interaction method. The search for each invention presents a serous burden, as the searches for each are not coextensive in scope. Art relating to the methods of determining the level of expression would not necessarily provide descriptive information on the polypeptide array itself, and vice versa.

8. Inventions III and IV are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the groups are drawn to distinct methods, which have different goals and modes of operations. The methods share a common step wherein they measure expression levels of nuclear encoded mitochondrial energy metabolism molecules. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion. The method of using a polypeptide microarray does not require the same steps as a method utilizing a nucleic acid array.

9. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case Invention I is drawn to an array of nucleic acids of proteasomal molecule and Invention II is drawn to a polypeptide array of proteasomal molecule. The inventions share a common step in which both the nucleic acids and polypeptides are bound to an array, however, the inventions are distinct because they are drawn to patentably distinct products, which have different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phospodiester bonds and assumes the form of a double helix. The polypeptides of Group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The reagents, reaction conditions, and reaction parameters for nucleic acid arrays and polypeptide arrays are different from each other. The search for each of the groups presents a serious search burden, as the searches for each are not coextensive in scope. Art describing polynucleotides would not necessarily describe polynucleotides of the same fragments, and vice versa.

10. Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of proteasomal molecule molecules could be used in the method of determining the level of expression or can be used in a haplotyping method. The search for each invention presents a serous burden, as the searches for each are not coextensive in

scope. Art relating to the methods of determining the level of expression would not necessarily provide descriptive information on the nucleic acid array itself, and vice versa.

11. Inventions V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid microarray and a method of measuring expression levels of a polypeptide microarray. There is no indication in the claims that the product of Invention V is used in the method of Invention VIII and therefore there is no relationship between the two inventions.

12. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a polypeptide microarray and a method of measuring expression levels of a nucleic acid microarray. There is no indication in the claims that the product of Invention VI is used in the method of Invention VII and therefore there is no relationship between the two inventions.

13. Inventions VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides

of proteasomal molecules could be used in the method of determining the level of expression or can be used in an antibody interaction method. The search for each invention presents a serous burden, as the searches for each are not coextensive in scope. Art relating to the methods of determining the level of expression would not necessarily provide descriptive information on the polypeptide array itself, and vice versa.

14. Inventions VII and VIII are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the groups are drawn to distinct methods, which have different goals and modes of operations. The methods share a common step wherein they measure expression levels of proteasomal molecules. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion. The method of using a polypeptide microarray does not require the same steps as a method utilizing a nucleic acid array.

15. Inventions IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention I is drawn to an array of nucleic acids of Table 4 molecules and Invention II is drawn to a polypeptide array of Table 4 molecules. The inventions share a common step in which both the nucleic acids and polypeptides are bound to an

array, however, the inventions are distinct because they are drawn to patentably distinct products, which have different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phospodiester bonds and assumes the form of a double helix. The polypeptides of Group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The reagents, reaction conditions, and reaction parameters for nucleic acid arrays and polypeptide arrays are different from each other. The search for each of the groups presents a serious search burden, as the searches for each are not coextensive in scope. Art describing polynucleotides would not necessarily describe polynucleotides of the same fragments, and vice versa.

16. Inventions IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Table 4 molecules could be used in the method of determining the level of expression or can be used in a haplotyping method. The search for each invention presents a serous burden, as the searches for each are not coextensive in scope. Art relating to the methods of determining the level of expression would not necessarily provide descriptive information on the nucleic acid array itself, and vice versa.

17. Inventions IX and XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid microarray and a method of measuring expression levels of a polypeptide microarray. There is no indication in the claims that the product of Invention IX is used in the method of Invention XII and therefore there is no relationship between the two inventions.

18. Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a polypeptide microarray and a method of measuring expression levels of a nucleic acid microarray. There is no indication in the claims that the product of Invention X is used in the method of Invention XI and therefore there is no relationship between the two inventions.

19. Inventions X and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Table 4 molecules could be used in the method of determining the level of expression or can be used in an antibody interaction method. The search for each invention presents a serous burden, as the searches for each are not coextensive in scope. Art

relating to the methods of determining the level of expression would not necessarily provide descriptive information on the polypeptide array itself, and vice versa.

20. Inventions XI and XII are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the groups are drawn to distinct methods, which have different goals and modes of operations. The methods share a common step wherein they measure expression levels of Table 4 molecules. Beyond this commonality, however, the methods are distinct from one another because they have different goals and would require different additional process steps, reagents, and analyses for their completion. The method of using a polypeptide microarray does not require the same steps as a method utilizing a nucleic acid array.

21. Additionally, Inventions I-XII named above are subject to **further restrictions**. Applicant is required in Inventions I, III, V, VII, IX, and XI to further elect a specific nucleic acid molecule or a specific combination of nucleic acid molecules directed to the elected gene type (nuclear encoded mitochondrial energy metabolism, proteasomal, or Table 4). Applicant is required in Inventions III, IV, VI, VIII, X, and XII to further elect a specific polypeptide or a specific combination of polypeptides directed to the elected gene type (nuclear encoded mitochondrial energy metabolism, proteasomal, or Table 4). **This is NOT an election of species**. Each nucleic acid or polypeptide or combination of nucleic acids or combination of polypeptides is drawn to structurally distinct molecules. These sequences are thus deemed to normally constitute

independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid sequence or combination; or polypeptide sequence or combination are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute, "[I]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences or combination of in the alternative, represents a serious burden for the office.

22. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

23. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because inventions I-XII require different searches that are not coextensive, examination of these claims would pose a serious

burden on the examiner and therefore restriction for examination purposes as indicated is proper.

24. A telephone call was made to Karen Elbing on 2/17/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

25. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday -Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 2/21/2006
Katherine Salmon
Examiner
Art Unit 1634

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER